Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Clinical practice guideline (update): earwax (cerumen impaction).

Bibliographic Source(s)

Schwartz SR, Magit AE, Rosenfeld RM, Ballachanda BB, Hackell JM, Krouse HJ, Lawlor CM, Lin K, Parham K, Stutz DR, Walsh S, Woodson EA, Yanagisawa K, Cunningham ER Jr. Clinical practice guideline (update): earwax (cerumen impaction). Otolaryngol Head Neck Surg. 2017 Jan;156 (Suppl 1):S1-S29. [121 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Roland PS, Smith TL, Schwartz SR, Rosenfeld RM, Ballachanda B, Earll JM, Fayad J, Harlor AD Jr, Hirsch BE, Jones SS, Krouse HJ, Magit A, Nelson C, Stutz DR, Wetmore S. Clinical practice guideline: cerumen impaction. Otolaryngol Head Neck Surg. 2008 Sep;139(3 Suppl 2):S1-21. [97 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests

	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▮▯	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▯	Search Strategy
▮▮▮▮▯	Study Selection
▮▮▮▯▯	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▯	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▮▮▯	External Review
▮▮▮▮▮	Updating

Recommendations

Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation, and Option) are defined at the end of the "Major Recommendations" field.

Statement 1. Primary Prevention

Clinicians should explain proper ear hygiene to prevent cerumen impaction when patients have an accumulation of cerumen.

Recommendation based on observational studies and a preponderance of benefit over harm.

Action Statement Profile

Quality improvement opportunity: Communicating safe preventive measures to patients (National Quality Strategy domain: patient and family engagement)
Aggregate evidence quality: Grade C, based on preponderance of survey studies and 1 prospective pilot study
Level of confidence in evidence: Medium

Benefit: Promote safe and effective self-care behaviors in ear hygiene; prevent self-inflicted harms, such as abrasions, cuts, and impaction; reduction in health care utilization
Risks, harms, costs: Induced patient anxiety regarding an asymptomatic condition; time spent in counseling; potential for increased use of health care resources if self-cleaning with cotton-tipped applicators is abandoned
Benefit-harm assessment: Preponderance of benefit
Value judgments: Perception by the group that patients overmanipulate the ears (i.e., cotton swab use) and that there is benefit in educating patients about proper ear hygiene
Intentional vagueness: The term *proper ear hygiene* is used and is discussed in detail in the text. The term *accumulation* is used but not precisely defined, as it is up to the clinician to determine. This statement applies to patients with impacted cerumen and those who are at risk.
Role of patient preferences: Small; patient can decline education
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 2A. Diagnosis of Cerumen Impaction

Clinicians should diagnose cerumen impaction when an accumulation of cerumen, as seen with otoscopy, 1) is associated with symptoms, 2) prevents needed assessment of the ear, or 3) both.

Recommendation based on diagnostic studies with minor limitations and a preponderance of benefit over harm.

Action Statement Profile:

Quality improvement opportunity: Allow for accurate diagnosis and properly identify patients in need of treatment (National Quality Strategy domain: clinical processes/effectiveness)
Aggregate evidence quality: Grade B for diagnostic studies with minor limitations regarding impact of cerumen on hearing and visualizations and grade C with respect to signs and symptoms associated with cerumen impaction
Level of confidence in evidence: High
Benefit: Identify individuals with cerumen impaction who require intervention, including those with otologic symptoms and those who require diagnostic assessment (raise awareness of the consequences of cerumen impaction—e.g., cerumen impaction prevents caloric stimulation during electronystagmography)
Risks, harms, costs: Overdiagnosis of cerumen impaction based on symptoms as a criterion resulting in failure to identify another cause of the symptoms; no additional cost
Benefits-harm assessment: Preponderance of benefits over harms
Value judgments: Emphasis on clinical symptoms and signs for initial diagnosis; importance of avoiding unnecessary diagnostic tests; consensus on using the term *cerumen impaction* to imply cerumen that requires treatment
Intentional vagueness: Symptoms are defined in the supporting text (see the original guideline document); prevention of needed assessments is defined by the clinician
Role of patient preferences: None
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 2B. Modifying Factors

Clinicians should assess the patient with cerumen impaction by history and/or physical examination for factors that modify management such as ≥1 of the following: anticoagulant therapy, immunocompromised state, diabetes mellitus, prior radiation therapy to the head and neck, ear canal stenosis, exostoses, nonintact tympanic membrane.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile:

Quality improvement opportunity: Avoiding harms from intervention in people at increased risk based on patient characteristics (National Quality Strategy domain: patient safety)
Aggregate evidence quality: Grade C, recommendations regarding diabetes mellitus and prior radiation therapy; Grade D, recommendations regarding immunocompromised state, anticoagulation, and anatomic abnormalities of the ear canal and tympanic membrane
Level of confidence in evidence: Medium
Benefit: Reduce complications
Risks, harms, costs: Time of the assessment
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: Consensus that identifying modifying factors will improve outcomes
Intentional vagueness: None
Role of patient preferences: None
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 3A. Need for Intervention if Impacted

Clinicians should treat, or refer to another clinician who can treat, cerumen impaction when identified.

Strong recommendation based on randomized controlled trials (RCTs) with heterogeneity with a preponderance of benefit over harm.

Action Statement Profile:

Quality improvement opportunity: Prioritize patients for intervention (National Quality Strategy domain: clinical processes/effectiveness)
Aggregate evidence quality: Grade B, RCTs with heterogeneity
Level of confidence in the evidence: High
Benefit: Improved hearing and symptom relief compared with no treatment
Risks, harms, costs: Potential complications related to treatment; direct cost of managing the impaction
Benefits-harm assessment: Preponderance of benefit over harm
Value judgments: None
Intentional vagueness: None
Role of patient preferences: Small
Exceptions: None
Policy level: Strong recommendation
Differences of opinion: None

Statement 3B. Nonintervention if Asymptomatic

Clinicians should not routinely treat cerumen in patients who are asymptomatic and whose ears can be adequately examined.

Recommendation against based on control groups in randomized trials and observational studies and a preponderance of benefit over harms.

Action Statement Profile:

Quality improvement opportunity: Avoidance of harm, efficient use of health care resources (National Quality Strategy domains: patient safety and efficient use of health care resources)
Aggregate evidence quality: Grade C, control groups in randomized trials and observational studies
Level of confidence in the evidence: Medium
Benefit: Avoid unnecessary treatment with potential adverse events and costs
Risks, harms, costs: Potential progression to impaction

Benefit-harm assessment: Preponderance of benefit over harms
Value judgments: The presence of cerumen is not in itself harmful, and it may not progress to impaction; in fact, it may resolve spontaneously. If it progresses, it can be managed at that time.
Intentional vagueness: The word *routinely* was added to this statement to acknowledge that there may be circumstances where cerumen removal may be offered anyway, as in a patient with hearing aids.
Role of patient preferences: Substantial role for shared decision making. The patient may still opt for removal of the cerumen.
Exceptions: Medical reasons for exceptions to this statement include, but are not limited to, history of recurrent cerumen impaction
Policy level: Recommendation against
Differences of opinion: None

Statement 3C. Need for Intervention in Special Populations

Clinicians should identify patients with obstructing cerumen in the ear canal who may not be able to express symptoms (young children and cognitively impaired children and adults), and they should promptly evaluate the need for intervention.

Recommendation based on cohort and observational studies with a preponderance of benefit over harm.

Action Statement Profile:

Quality improvement opportunity: Efficient use of health care resources and coordination of care (National Quality Strategy domains: care coordination and efficient use of health care resources)
Aggregate evidence quality: Grade C, cohort and observational studies
Level of confidence in the evidence: High
Benefit: Improved hearing and functional health status; improved evaluation of external auditory canal, tympanic membrane, and middle ear
Risks, harms, costs: Potential overtreatment of cerumen that is asymptomatic; evaluation and treatment costs; substantial administrative burden in settings with a high prevalence of cognitively impaired individuals, such as nursing homes and institutional facilities
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: Importance of identifying and treating cerumen impaction in special populations
Intentional vagueness: The term *young children* does not specify age but rather indicates children who are unable or too immature to express symptoms or who fail to disclose real symptoms out of fear of treatment. Additionally, the term *promptly* does not specify a time frame but allows for clinical judgment regarding how expedient the evaluation should be.
Role of patient preferences: None for the patient but moderate for patient advocates
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 4. Intervention in Hearing Aid Users

Clinicians should perform otoscopy to detect the presence of cerumen in patients with hearing aids during a health care encounter.

Recommendation based on cohort and observational studies with a preponderance of benefit over harm.

Action Statement Profile:

Quality improvement opportunity: Effective use of health care resources and prevention of problems with hearing aid use in high-risk populations (National Quality Strategy domains: efficient use of health care resources and clinical processes/effectiveness)
Aggregate evidence quality: Grade C, observational studies
Level of confidence in the evidence: High
Benefit: Prevent hearing aid dysfunction and associated repair costs

Risks, harms, costs: Overtreatment of asymptomatic cerumen
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: Cerumen can have a disproportionate effect on patients with hearing aids due to their underlying hearing loss and the impact of the cerumen on the hearing aids, even if there is not an actual impaction.
Intentional vagueness: The term *health care encounter* is somewhat vague but is intended to indicate any time that a patient with a hearing aid is assessed by a health care worker.
Role of patient preferences: Small
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 5A. Recommended Interventions

Clinicians should treat, or refer to a clinician who can treat, the patient with cerumen impaction with an appropriate intervention, which may include one or more of the following: cerumenolytic agents, irrigation, or manual removal requiring instrumentation.

Recommendation based on RCTs and observational studies with a preponderance of benefit over harm.

Action Statement Profile

Quality improvement opportunity: Engage patient and family; promote the use of effective therapy (National Quality Strategy domains: patient and family engagement and clinical processes/effectiveness)
Aggregate evidence quality: Grade B, RCTs with limitations and cohort studies
Level of confidence in the evidence: High
Benefit: Improved cerumen removal by using effective therapies and to avoid harm from ineffective or untested therapies
Risks, harms, cost: Specific adverse effects related to treatments used; no cost associated with the decision to use appropriate therapy
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: Therapy should be effective and minimize harm
Intentional vagueness: This does not specify one method as superior, as studies have not compared them head-to-head and all may be effective.
Role of patient preferences: Large
Exceptions: Irrigation and cerumenolytics should not be used in the setting of a nonintact tympanic membrane.
Policy level: Recommendation
Differences of opinion: None

Statement 5B. Contraindicated Intervention (Ear Candling/Coning)

Clinicians should recommend against ear candling/coning for treating or preventing cerumen impaction.

Recommendation against based on RCTs and observational studies with a preponderance of benefit over harm.

Action Statement Profile

Quality improvement opportunity: Reducing harm and avoiding ineffective treatments (National Quality Strategy domain: patient safety and clinical processes/effectiveness)
Aggregate evidence quality: Grade C
Level of confidence in evidence: Medium
Benefit: Avoid ineffective therapy; avoid harms; cost savings; prevent delay of effective therapy
Risks, harms, costs: None
Benefit-harm assessment: Preponderance of benefit
Value judgments: Strong consensus of the group to avoid potentially harmful and costly therapies

with no proven benefit
Intentional vagueness: None
Role of patient preferences: None
Exclusions: None
Policy level: Recommendation against
Differences of opinion: None

Statement 6. Cerumenolytic Agents

Clinicians may use cerumenolytic agents (including water or saline solution) in the management of cerumen impaction.

Option based on limited randomized trials with a balance of benefit and harm.

Action Statement Profile:

Quality improvement opportunity: Encourage use of effective care; promote effective therapy (National Quality Strategy domain: clinical processes/effectiveness)
Aggregate evidence quality: Grade C, individual treatment arms of randomized trials showing beneficial outcomes, 1 RCT suggesting better outcomes over no treatment
Level of confidence in the evidence: High
Benefit: Safe and effective removal of impacted cerumen
Risks, harms, costs: Potential external otitis, allergic reactions, and otalgia; cost of cerumenolytic agents other than water or saline solution, cost of procedure if performed in an office setting
Benefit-harm assessment: Balance of benefit and harm
Value judgments: The panel values cost control and safety in view of limited data on absolute and comparative efficacy
Intentional vagueness: None
Role of patient preferences: Large role for shared decision making
Exceptions: Medical reasons for exceptions to this statement include, but are not limited to, persons with a history of allergic reactions to any component, persons with infection of the ear canal or active dermatitis, and persons with a nonintact tympanic membrane.
Policy level: Option
Differences of opinion: None

Statement 7. Irrigation

Clinicians may use irrigation in the management of cerumen impaction.

Option based on RCTs with heterogeneity and with a balance of benefit and harm.

Action Statement Profile:

Quality improvement opportunity: Promote effective therapy (National Quality Strategy domain: clinical processes/effectiveness)
Aggregate evidence quality: Grade B, 1 RCT verifying absolute efficacy but multiple treatment arms of comparative studies verifying benefit over cerumenolytic alone
Level of confidence in the evidence: High
Benefit: Resolve cerumen impaction
Risks, harms, costs: External otitis, vertigo, tympanic membrane perforation, otalgia, temporal bone osteomyelitis; cost of supplies and procedure
Benefit-harm assessment: Balance of benefit and harm
Value judgments: Panel enthusiasm was tempered by the lack of appropriate head-to-head trials comparing irrigation to manual removal or cerumenolytics
Intentional vagueness: None
Role of patient preferences: Large
Exceptions: Medical reasons for exceptions to this statement include, but are not limited to, persons with open tympanic membrane, active dermatitis or infection of the ear canal and surrounding tissue,

previous intolerance or adverse reaction to this technique, anatomic abnormalities of the ear canal, or history of surgery of the ear or ear canal (including ear tubes).
Policy level: Option
Differences of opinion: None

Statement 8. Manual Removal

Clinicians may use manual removal requiring instrumentation in the management of cerumen impaction.

Option based on case series and expert opinion with a balance of benefit and harm.

Action Statement Profile

Quality improvement opportunity: Promote effective therapy (National Quality Strategy domain: clinical processes/effectiveness)
Aggregate evidence quality: Grade C, observational case series and expert opinion
Level of confidence in the evidence: High
Benefit: Removal of cerumen impaction under direct visualization
Risks, harms, costs: Bleeding, laceration, tympanic membrane perforation, otalgia; procedural cost; equipment cost
Benefit-harm assessment: Balance of benefit and harm
Value judgments: Recommendation acknowledges widespread practice of manual removal, but this is tempered by the relative absence of evidence
Intentional vagueness: None
Role of patient preferences: Large
Exceptions: None
Policy level: Option
Differences of opinion: None

Statement 9. Outcomes Assessment

Clinicians should assess patients at the conclusion of in-office treatment of cerumen impaction and document the resolution of impaction. If the impaction is not resolved, the clinician should use additional treatment. If full or partial symptoms persist despite resolution of impaction, the clinician should evaluate the patient for alternative diagnoses.

Recommendation based on RCTs with limitations (supporting a failure of clearance of cerumen in some cases) and with a preponderance of benefit over harm.

Action Statement Profile

Quality improvement opportunity: Ensuring effectiveness of treatment to optimize patient outcomes and ensuring accurate diagnosis of cause of symptoms (National Quality Strategy domain: clinical processes/effectiveness)
Aggregate evidence quality: Grade C. Observation in treatment arms of several randomized trials show that retreatment is sometimes necessary and can be effective; first principles support evaluation for efficacy after treatment.
Level of confidence in the evidence: High
Benefit: Detect complications; encourage proper diagnosis; ensure effective therapy
Risks, harms, costs: See sections on individual treatments; cost of additional treatment or evaluation
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: Importance of clinician assessment after treatment; avoid misdiagnosis
Intentional vagueness: The term *additional treatment* does not specify what type of treatment. Additional treatment can include repeating the same treatment or trying an alternative method (i.e., manual removal if irrigation was tried first or use of softening agents if not used initially).
Role of patient preferences: Small
Exceptions: None

Policy level: Recommendation
Differences of opinion: None

Statement 10. Referral and Coordination of Care

If initial management is unsuccessful, clinicians should refer patients with persistent cerumen impaction to clinicians who have specialized equipment and training to clean and evaluate ear canals and tympanic membranes.

Recommendation based on individual arms of randomized trials and preponderance of benefit over harm.

Action Statement Profile

Quality improvement opportunity: Coordination of care and effective treatment (National Quality Strategy domains: care coordination and clinical processes/effectiveness)
Aggregate evidence quality: Grade C, individual arms of randomized trials
Level of confidence in evidence: High
Benefit: Promote successful removal of cerumen impaction; timely coordination of care; avoidance of harm from repeated unsuccessful interventions; avoid patient and clinician frustration; avoiding misdiagnosis
Risks, harms, costs: Cost of additional care; limited access to specialty care
Benefit-harm assessment: Preponderance of benefit
Value judgments: Skill and instruments will promote a better outcome. The level of care that can be rendered can be limited by the available equipment and training.
Intentional vagueness: The specialized equipment and training are vague but may include access to binocular microscopy, suction, microinstruments, or the operating room. Type of training is not specified, but this refers to someone with advanced capabilities of removing cerumen. Unsuccessful treatment may entail a repeat visit or multiple treatments by the initial clinician to allow for use of softening agents or spontaneous improvement of impacted cerumen.
Role of patient preferences: Small
Exclusions: None
Policy level: Recommendation
Differences of opinion: None

Statement 11. Secondary Prevention

Clinicians may educate/counsel patients with cerumen impaction or excessive cerumen regarding control measures.

Option based on survey and comparative studies with unclear balance of benefit vs harm.

Action Statement Profile

Quality improvement opportunity: Patient and family engagement (National Quality Strategy domain: patient and family engagement)
Aggregate evidence quality: Grade C; observational studies, experimental pilot studies, and expert opinion
Level of confidence in the evidence: High
Benefit: Prevent development of cerumen impaction or recurrent cerumen impaction
Risks, harms, costs: Time for counseling and potential risk of preventive measures if used
Benefit-harm assessment: Balance benefit over harm
Value judgments: Importance of prevention in managing patients with cerumen impaction
Intentional vagueness: The term *excessive cerumen* is used to indicate when cerumen is present but not actively causing symptoms, to allow the clinician freedom to counsel patients who appear to be at risk for cerumen impaction even when the ear is not actually impacted.
Role of patient preferences: Large, opportunities for shared decision making
Exceptions: None
Policy level: Option

Differences of opinion: None

Definitions

Aggregate Grades of Evidence by Question Type[a]

Grade	Treatment	Diagnosis	Prognosis
A	Systematic review[b] of randomized trials	Systematic review[b] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[b] of inception cohort studies[c]
B	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[c]
C	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor-quality prognostic cohort study
D	Case reports, mechanism-based reasoning, or reasoning from first principles		
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm		

[a]American Academy of Otolaryngology—Head and Neck Surgery Foundation guideline development manual (see the "Availability of Companion Documents" field).

[b]A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

[c]A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Strength of Action Terms in Guideline Statements and Implied Levels of Obligation

Strength	Definition	Implied Obligation
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (grade A or B).[a] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of evidence is not as high (grade B or C).[a] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive or patient preferences.
Option	An option means that either the quality of evidence is suspect (grade D)[a] or that well-done studies (grade A, B, or C)[a] show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

Strength	Definition	Implied Obligation

[a]See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Clinical Algorithm(s)

An algorithm titled "Algorithm showing the interrelationship of guideline key action statements (KASs)" is provided in the original guideline document.

Scope

Disease/Condition(s)

Cerumen impaction, defined as an accumulation of cerumen that causes symptoms or prevents a needed assessment of the ear canal, tympanic membrane, or audiovestibular system, or both

Guideline Category

Diagnosis

Management

Prevention

Treatment

Clinical Specialty

Family Practice

Geriatrics

Nursing

Otolaryngology

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To update the original multidisciplinary guideline by examining previously and newly identified

quality improvement opportunities in the management of impacted cerumen
- To help clinicians identify patients with cerumen impaction who may benefit from intervention and to promote evidence-based management
- To highlight needs and management options in special populations or in patients who have modifying factors
- To create a guideline suitable for deriving a performance measure on cerumen impaction

Target Population

Patients >6 months of age with a clinical diagnosis of cerumen impaction

Note: The guideline does *not* apply to patients with cerumen impaction associated with the following conditions: dermatologic diseases of the ear canal; recurrent otitis externa; keratosis obturans; prior radiation therapy affecting the ear; exostoses or osteoma; neoplasms of the ear canal; previous tympanoplasty/myringoplasty, canal wall down mastoidectomy, or other surgery affecting the ear canal. However, the guideline discusses the relevance of these conditions in cerumen management. The following modifying factors are not the primary focus of the guideline but are discussed relative to their impact on management: nonintact tympanic membrane (perforation or tympanostomy tube), ear canal stenosis, exostoses, diabetes mellitus, immunocompromised state, anticoagulant therapy, or bleeding disorder.

Interventions and Practices Considered

Diagnosis/Evaluation

Targeted history and physical examination for patient factors that may modify management
Otoscopy
Binocular microscopy
Identifying need for interventions in special populations (e.g., young children and cognitively impaired children and adults)

Treatment/Management/Prevention

Education on proper hygiene
Cerumenolytic agents
Ear canal irrigation
Manual removal other than irrigation (curette, probe, forceps, suction, hook)
Ear candling/coning (contraindicated)
Outcomes assessment
Referral and coordination of care

Major Outcomes Considered

- Resolution or change in the signs and symptoms associated with cerumen impaction
- Complications/adverse events
- Cost
- Adherence to therapy
- Quality of life
- Return to work or activity
- Return physician visits
- Effect on comorbid conditions (e.g., sensorineural hearing loss, conductive hearing loss)

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A literature search was performed by an information specialist to identify systematic reviews, clinical practice guidelines, and randomized controlled trials (RCTs) published since the prior guideline cutoff (September 2007). The following databases were searched from October 2007 to April 2015: MEDLINE (OvidSP), EMBASE (OvidSP), AMED (OvidSP), Cumulative Index to Nursing and Allied Health, PubMed, National Guideline Clearinghouse, and Cochrane Controlled Trials Register. The databases were searched for the topic of interest with use of controlled vocabulary words and synonymous free text words (cerumen, earwax, and impaction). The search strategies were adjusted for the syntax appropriate for each database/platform.

The initial English-language search identified 1 potential clinical practice guideline, 7 systematic reviews, 5 RCTs and 10 other studies. All searches were conducted on April 3, 2015. Clinical practice guidelines were included if they met quality criteria of (a) an explicit scope and purpose, (b) multidisciplinary stakeholder involvement, (c) systematic literature review, (d) explicit system for ranking evidence, and (e) explicit system for linking evidence to recommendations. Systematic reviews were emphasized and included if they met quality criteria of (a) clear objective and methodology, (b) explicit search strategy, and (c) valid data extraction methods. RCTs were included if they met quality criteria of (a) trials involved study randomization, (b) trials were described as double blind, or (c) trials denoted a clear description of withdrawals and dropouts of study participants. Additional evidence was identified, as needed, with targeted searches to support needs of the guideline development group in updating sections of the guideline text. Specifically, ear candling/coning was identified as an area of concern by the reviewers. The databases were also searched through use of controlled vocabulary words and synonymous free text words for the topic of interest (ear candling and ear coning) in this population. The search strategies were adjusted for the syntax appropriate for each database/platform. The search was not limited by date range or study design, but was limited to English language.

Number of Source Documents

In total, the evidence supporting this guideline includes 1 clinical practice guideline, 4 systematic reviews, and 5 randomized control trials.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Aggregate Grades of Evidence by Question Type[a]

Grade	Treatment	Diagnosis	Prognosis
A	Systematic review[b] of randomized trials	Systematic review[b] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[b] of inception cohort studies[c]
B	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[c]

Grade	Treatment	Diagnosis	Prognosis
C	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor-quality prognostic cohort study
D	Case reports, mechanism-based reasoning, or reasoning from first principles		
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm		

[a]American Academy of Otolaryngology—Head and Neck Surgery Foundation guideline development manual (see the "Availability of Companion Documents" field).

[b]A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

[c]A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized, and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the *quality of evidence* and the *balance of benefit and harm* that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in "Ratings Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The guideline update was developed with an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm, as outlined in the "Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence into Action" (see the "Availability of Companion Documents" field).

The original cerumen impaction guideline was first sent to a panel of expert reviewers, who were asked (1) to assess the key action statements and decide if they should be revised, kept as stands, or removed on the basis of relevancy, omissions, or controversies that the guideline spurred and (2) to identify any new literature or treatments that might affect the guideline recommendations. The reviewers concluded that the original guideline action statements remained valid but should be updated with minor modifications. A suggestion was also made for a new key action statement on the role of alternative therapies in management.

The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) assembled a Guideline Update Group (GUG) representing the disciplines of otolaryngology–head and neck surgery, otology/neurotology, family medicine, audiology, advanced practice nursing, pediatrics, geriatrics, a resident physician (otolaryngology), and a consumer advocate. The GUG also included a staff liaison from the AAO-HNSF, but this individual was not a voting member of the GUG and served only in an editorial

capacity in writing the guideline. Several group members had significant prior experience in developing clinical practice guidelines.

The GUG had several conference calls and one in-person meeting, during which comments from the expert panel review and the literature search were reviewed for each key action statement. The GUG then decided to leave the statements unaltered, change slightly, or rewrite per the impact of the literature search, the reviewer comments, and the benefit-harm balance. The supporting text was then edited to explain any changes from the original key action statement, and the recommendation level was modified accordingly.

The evidence profile for each statement was then converted into an action statement profile, which was moved to immediately follow the action statement. Statements about the quality improvement opportunity, level of confidence in the evidence, differences of opinion, intentional vagueness, and any exclusion to which the action statement does not apply were added to the action statement profiles. These additions reflect the current methodology for guideline development by the AAO-HNSF and conform to the Institute of Medicine's standards for developing trustworthy guidelines. The updated guideline then underwent GuideLine Implementability Appraisal to appraise adherence to methodologic standards, improve clarity of recommendations, and predict potential obstacles to implementation. The GUG received summary appraisals in October 2015 and modified an advanced draft of the guideline on the basis of the appraisal.

Rating Scheme for the Strength of the Recommendations

Strength of Action Terms in Guideline Statements and Implied Levels of Obligation

Strength	Definition	Implied Obligation
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (grade A or B).[a] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of evidence is not as high (grade B or C).[a] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive or patient preferences.
Option	An option means that either the quality of evidence is suspect (grade D)[a] or that well-done studies (grade A, B, or C)[a] show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

[a]See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The final draft of the updated clinical practice guideline was revised according to comments received during multidisciplinary peer review, open public comment, and journal editorial peer review.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Improved diagnostic accuracy for cerumen impaction
- Appropriate intervention in patients with cerumen impaction
- Appropriate evaluation and intervention in special populations
- Appropriate therapeutic options with outcomes assessment
- Improved counseling and education for prevention of cerumen impaction

For additional benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

Though generally safe, treatment of cerumen impaction can result in significant complications. Tympanic membrane perforation, ear canal laceration, infection of the ear, bleeding, or hearing loss occurs at a rate of about 1 in 1000 ear irrigations. Applying this rate to the approximate number of ear irrigations performed in the United States estimates that 8000 complications occur annually and likely require further medical services. Other complications that have been reported include otitis externa (sometimes secondary to external auditory canal trauma), pain, dizziness, and syncope.

For additional possible harms of specific interventions considered in the guideline, see the "Major Recommendations" field.

Contraindications

Contraindications

- Contraindicated intervention (ear candling/coning): Clinicians should recommend against ear candling/coning for treating or preventing cerumen impaction.
- If the ear canal is currently infected, irrigation should be avoided. Ear irrigation should not be performed in individuals who have a nonintact tympanic membrane or those who have had ear surgery, since the tympanic membrane may be thinned or atrophic and vulnerable to perforation.
- Jet irrigators should be avoided for home use due to risk of damage to ear structures.

Refer to the "Exceptions" statements in the "Action Statement Profiles" for additional guidance on medical reasons to avoid certain interventions or procedures.

Qualifying Statements

Qualifying Statements

- The clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing cerumen impaction. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions, but they are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology—Head and Neck Surgery Foundation, Inc emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.
- Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less-frequent variation in practice is expected for a strong recommendation than what might be expected with a recommendation. Options offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.
- Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline update group (GUG) sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the GUG was to be transparent and explicit about how values were applied and to document the process.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Considerations

The complete guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery* to facilitate reference and distribution. A full-text version of the guideline will also be accessible free of

charge at the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) Web site . Existing brochures and publications by the AAO-HNSF will be updated to reflect the guideline recommendations.

An anticipated barrier to diagnosis is distinguishing modifying factors for cerumen impaction in a busy clinical setting. This will be addressed with a laminated teaching card or visual aid summarizing important factors that modify management. Laminated cards will be available for purchase through Guideline Central.

An anticipated barrier to the "observation option" for nonimpacted cerumen is patient and clinician reluctance to not intervene when cerumen is observed. This barrier can be overcome with educational pamphlets and information sheets that outline the favorable natural history of nonimpacted cerumen, the moderate incremental benefit of removal on clinical outcomes, the potential adverse effects of treatment, and the benefits of cerumen for a healthy ear canal.

Prompt evaluation of special populations may be hindered by the high prevalence of cerumen impaction in these populations and additional treatment time that may be necessary in busy practice settings. Information sheets outlining the high prevalence and the potential morbidity of cerumen impaction in these populations may increase awareness and willingness to manage this problem.

Performance of irrigation and instrument removal other than irrigation, when appropriate, may be hindered by access to equipment and by procedural cost. Lastly, successfully achieving an understanding of the lack of efficacy and potential harms of ear candling, a popular alternative therapy, will require patient and clinician access to educational materials. Pamphlets may help in dispelling myths about comparative efficacy.

Implementation Tools

Clinical Algorithm

Foreign Language Translations

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Schwartz SR, Magit AE, Rosenfeld RM, Ballachanda BB, Hackell JM, Krouse HJ, Lawlor CM, Lin K, Parham K, Stutz DR, Walsh S, Woodson EA, Yanagisawa K, Cunningham ER Jr. Clinical practice guideline (update): earwax (cerumen impaction). Otolaryngol Head Neck Surg. 2017 Jan;156 (Suppl 1):S1-S29. [121 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Jan

Guideline Developer(s)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

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Guideline Committee

American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Guideline Update Group (GUG)

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Financial Disclosures/Conflicts of Interest

Financial Disclosure and Conflicts of Interest

Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call and were updated at each subsequent call and in-person meeting. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed to not discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

Disclosures

Competing interests: Bopanna B. Ballachanda, chief of Audiology and consultant for Audiology Management Group; Jesse M. Hackell, shareholder of Pfizer and GSK, expert witness, medical malpractice consultant; Helene J. Krouse, AAO-HNSF journal editor, spouse on AAO-HNSF Board of Directors, Sohn research funding; Erika A. Woodson, consultant for Oticon Medical, speaker honoraria for CitiGroup; Eugene R. Cunningham Jr, salaried employee of AAO-HNSF.

Guideline Endorser(s)

American Academy of Family Physicians - Medical Specialty Society

American Academy of Pediatrics - Medical Specialty Society

American Geriatrics Society - Medical Specialty Society

American Neurotology Society - Medical Specialty Society

American Otological Society - Medical Specialty Society

American Society of Geriatric Otolaryngology - Medical Specialty Society

American Society of Pediatric Otolaryngology - Medical Specialty Society

Society of Otorhinolaryngology and Head and Neck Nurses - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Roland PS, Smith TL, Schwartz SR, Rosenfeld RM, Ballachanda B, Earll JM, Fayad J, Harlor AD Jr, Hirsch BE, Jones SS, Krouse HJ, Magit A, Nelson C, Stutz DR, Wetmore S. Clinical practice guideline: cerumen impaction. Otolaryngol Head Neck Surg. 2008 Sep;139(3 Suppl 2):S1-21. [97 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the SAGE Journals Web site.

Availability of Companion Documents

The following are available:

Schwartz SR, Magit AE, Rosenfeld RM, Ballachanda BB, Hackell JM, Krouse HJ, Lawlor CM, Lin K, Parham K, Stutz DR, Walsh S, Woodson EA, Yanagisawa K, Cunningham ER. Clinical practice guideline (update): earwax (cerumen impaction) executive summary. Otolaryngol Head Neck Surg. 2017;156 (Suppl 1):14-29. Available from the SAGE Journals Web site.

Clinical practice guideline (update): earwax (cerumen impaction). Podcast part 1 and 2. Alexandria (VA): American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF). 2017 Jan. Available from the American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF) Web site.

Clinical practice guideline (update): earwax (cerumen impaction). Pocket guide and mobile app. Alexandria (VA): American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF). 2017 Jan. Available from the Guideline Central Web site.

Rosenfeld RM, Shiffman RN, Robertson P. Clinical practice guideline development manual, third edition: a quality-driven approach for translating evidence into action. Otolaryngol Head Neck Surg. 2013 Jan;148(Suppl 1):S1-55. Available from the SAGE Journals Web site.

Patient Resources

A variety of patient resources are available in English and Spanish from the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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